

COLLABORATIVE PROGRAM FOR THE IDENTIFICATION AND PREVENTION OF WORK-RELATED MUSCULOSKELETAL DISORDERS

RELEASE DATE: April 7, 2003

RFA: OH-03-006

Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH) (<http://www.cdc.gov/niosh/homepage.html>)

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER(S): 93.262

LETTER OF INTENT RECEIPT DATE: May 20, 2003

APPLICATION RECEIPT DATE: June 12, 2003

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PURPOSE OF THIS RFA

The National Institute for Occupational Safety and Health (NIOSH) invites applications for a Cooperative Agreement (U01) from single institutions or consortia of institutions which are capable of, and interested in, participating in a Musculoskeletal Disorders Consortium (MSDC).

The goal of the MSDC is to coordinate a prospective cohort study to quantify the risk of upper limb and low back musculoskeletal disorders at varying levels of exposure to physical job stressors (repetitive motion, forceful exertions, awkward postures, manual handling, etc.). This research will involve multiple work sites from the service and manufacturing industries with job tasks that represent a range of exposures to physical job stressors that can result in musculoskeletal disorders.

Under this RFA, one new extramural partner that demonstrates expertise in the evaluation of exposure response between low back disorders and the physical demands of lifting and manual handling tasks will be awarded a cooperative agreement and will participate in the MSDC.

RESEARCH OBJECTIVES

Background

Work-related Musculoskeletal Disorders (MSDs) remain a large and costly disease to our society even though there have been many advances in understanding the ergonomics of work. For 1996, the Bureau of Labor Statistics (BLS) reported that a total of 600,390 work-related musculoskeletal injury cases resulting in work absence or restriction were caused by overexertion and repetitive motion. Because the BLS annual survey does not cover approximately one-third of workers, this figure significantly underestimates the overall incidence of MSDs in the American workforce. Of all MSD cases, sixty-nine percent were low back or distal upper limb disorders. The magnitude of the problem in today's workforce is confirmed by workers' compensation data. For instance, in Washington State between 1990 and 1997, 27 percent of all workers' compensation claims and 46 percent of the cost of all claims resulted from non-traumatic musculoskeletal disorders of the neck, upper extremity or back. The results from this research program will provide practitioners in occupational health critical data that will facilitate their identification of job tasks that represent low, moderate and high risk for MSDs and that will provide a knowledge base for effective job design changes or interventions. Because of the limitations of cross-sectional and retrospective studies, it is widely agreed that a prospective cohort study design is the best approach for this problem.

This RFA builds on an initial effort in 2000 to begin a Collaborative Program for the Identification and Prevention of Work-related Musculoskeletal Disorders (see <http://grants.nih.gov/grants/guide/rfa-files/rfa-OH-00-003.html>). As a result of the initial RFA, awards were made to evaluate exposure response relationships between physical stressors and upper extremity and low back musculoskeletal disorders. A second RFA in 2002 expanded this program by awarding an additional cooperative agreement to evaluate upper extremity disorders (see <http://grants.nih.gov/grants/guide/rfa-files/RFA-OH-02-010.html>). The current RFA is focused on providing an additional award to expand the research effort on low back disorders in relation to varying levels of physical demand due to lifting and manual material handling. An integral part of this initiative is participation in a Musculoskeletal Disorders Consortium (MSDC). In order to achieve the goals of this program, it is important to have shared data elements among awardees that are managed in a uniform and compatible format. In addition, because much of the shared data elements are centered on job tasks and workers, a critical role of the MSDC is to assure that job tasks are studied using uniform exposure assessment methods and health assessment methods to identify MSDs. In order to accomplish that goal, the initial awardees established a Coordination Committee (CC), to serve as the main governing board for the conduct of this research program. The CC is comprised of one voting representative from each member of the consortium.

The new awardee under this current RFA will also be a voting member on the CC. The CC will continue to serve as an advisory body for the common or shared protocols to be used in the studies. NIOSH staff serves as non-voting members of the CC.

Goals

An important goal of this research program is to better define exposure-response relationships between job physical stressors and musculoskeletal disorders across manufacturing and service industries. Information regarding the utility of practical methods that could be readily employed by occupational safety and health practitioners, such as the NIOSH Lifting Equation and the American Conference of governmental Industrial Hygienists Threshold Limit Value for Hand Activity, is another anticipated outcome. In addition, it is anticipated that practitioners in occupational health will be able to use the results from this study to more quickly and reliably discriminate job tasks that represent low, moderate and high risk for musculoskeletal disorders. With such knowledge effective job design changes or interventions can be developed that reduce the burden of work-related musculoskeletal disorders.

In summary, the intent of the initial RFA (RFA: [OH-00-003](#)) was to assemble a cross-disciplinary, multi-institutional consortium to define exposure response relationships among physical job stressors and upper limb and low back MSDs. Three Cooperative agreements were awarded, one focused on upper extremity disorders, one focused on low back disorders and the third focused on hand-arm vibration. As a result of a second RFA (RFA: [OH-02-010](#)), one cooperative agreement was awarded that focused on upper extremity disorders. The intent of the current RFA is to support additional research that is focused on low back disorders in relation to multiple levels of physical demands related to lifting and manual handling tasks in the manufacturing or service industry.

USEFUL REFERENCES

National Institute for Occupational Safety and Health. National Occupational Research Agenda. Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No.96-115 <http://www.cdc.gov/niosh/nora.html>).

MECHANISM OF SUPPORT

This RFA will use NIH U01 award mechanism(s). As an applicant you will be solely responsible for planning, directing, and executing the proposed project. This RFA is a one-time solicitation. Future unsolicited, competing-continuation applications based on this project will compete with all investigator-initiated applications and will be reviewed according to the customary peer review procedures. The anticipated award date is September 30, 2003. Applications that are not funded in the competition described in this RFA may be resubmitted as NEW investigator-initiated applications using the standard receipt dates for NEW applications described in the instructions to the PHS 398 application.

This RFA uses just-in-time concepts. It also uses the modular as well as the non-modular budgeting formats (see <http://grants.nih.gov/grants/funding/modular/modular.htm>). Specifically, if you are submitting an application with direct costs in each year of \$250,000 or less, use the modular format. Otherwise follow the instructions for non-modular research grant applications.

This program does not require cost sharing as defined in the current NIH Grants Policy Statement at [http://grants.nih.gov/grants/policy/nihgps_2001/part i 1.htm](http://grants.nih.gov/grants/policy/nihgps_2001/part_i_1.htm).

The NIH (U01) is a cooperative agreement award mechanism in which the Principal Investigator retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with NIH staff being substantially involved as a partner with the Principal Investigator, as described under the section "Cooperative Agreement Terms and Conditions of Award".

FUNDS AVAILABLE

NIOSH intends to commit approximately \$500,000 in FY 2003 to fund one new cooperative agreement award in response to this RFA. If additional monies become available, an additional award may be made. An applicant may request a project period of up to three years and a budget for total costs (direct and indirect) up to \$500,000 per year. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of NIOSH provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Applicants should allocate funds for travel for two project staff to attend two CC meetings held during each project year.

ELIGIBLE INSTITUTIONS

You may submit (an) application (s) if your institution has any of the following characteristics:

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories.
- o Units of State and local governments
- o Eligible agencies of the Federal government
- o Domestic or foreign
- o Faith-based or community-based organizations

Note: Title 2 United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed program is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIOSH/CDC programs.

SPECIAL REQUIREMENTS

Applicants with established resources and facilities to recruit study sites and to enroll workers willing to participate in the study in a cost effective manner are encouraged.

The following should be addressed in a clear and organized manner (see also peer review criteria section):

- o Timeline: a detailed timeline for the proposed study must be included in the application.

- o In a separate section labeled , "Participant Notification of Study Results", the applicant should describe plans for notifying participants about their individual results and the overall results of the study.

- o Plan for sharing data with other members of the MSDC and using uniform exposure assessment methods and health assessment methods to identify MSDs.

Applicants should highlight unique expertise and/or unusual opportunities as related to the purpose of this RFA. Examples include, but are not limited to:

- o Expertise in specialized areas with potential applications to the issues/questions considered in this RFA, conducting epidemiologic field studies of working populations, experience in exposure assessment using practical field methods such as the NIOSH lifting equation; and collection of health outcome data at the workplace;

- o Access to specific work sites and working populations that are willing to participate in studies of work-related low back disorders;

- o Expertise in assessing work situations and individual job tasks in relation to the development of work-related low back disorders; and/or

- o Expertise in negotiating with work site management in field settings.

Coordination Committee and Annual MSDC Meetings

Applicants should include in their budget support for themselves and for at least one other person from their institutions integrally involved in the project to attend two Coordination Committee (CC) meetings of the MSDC each year. For budget preparation and project planning purposes, it should be assumed that these meetings will be of one or two days duration and will be held in Cincinnati, Ohio. The CC will determine later where and when recurring CC meetings will be held. The CC chair will coordinate the meetings to review and assess overall progress and provide the opportunity for investigators to exchange information and discuss research issues.

Cooperative Agreement Terms and Conditions of Award

The Terms and Conditions of Award, below, will be incorporated in the award issued as a result of this RFA. It is critical that each applicant include specific plans for responding to these terms. These special Terms of Award are in addition to and not in lieu of otherwise applicable OMB administrative guidelines and HHS Grant Administration Regulations at 45 CFR Parts 74 and 92.

The administrative and funding instrument used for this program is a cooperative agreement (U01), an "assistance" mechanism (rather than an "acquisition" mechanism) in which substantial NIOSH scientific and/or programmatic involvement with the awardee is anticipated during performance of the activity.

Under the cooperative agreement, the NIOSH purpose is to support and/or stimulate the recipient's activity by involvement in and otherwise working jointly with the award recipient in a partner role, but it is not to assume direction, prime responsibility, or a dominant role in the activity.

Consistent with this concept, the dominant role and prime responsibility for the activity resides with the awardee(s) for the project as a whole, although specific tasks and activities in carrying out the studies will be shared among the awardees and the NIOSH collaborators where appropriate, including the following:

1. Recipient Responsibilities

The recipient will coordinate project activities, scientifically and administratively at the awardee institution and at the other sites that may be supported by sub-contractors to this award. The applicant will have primary authority and responsibility to define objectives and approaches; to plan, conduct, and analyze data; and to publish results, interpretations, and conclusions of studies conducted under the terms and conditions of the cooperative agreement award. In addition, the applicant is responsible for coordination of the individual study with the CC. It is anticipated that recipients will utilize common approaches as agreed upon by the CC so that data can be combined. Recipient will:

- a. Enroll and follow the study participants and establish and maintain mechanisms to ensure that data collection and management procedures have necessary quality control and assure confidentiality of data.
- b. Serve as a permanent member of the CC.
- c. Develop and submit semiannual progress reports in a standard format that is agreed upon after an award is made.
- d. Provide program management oversight for the project.
- e. Notify study participants of the overall study results.

2. NIOSH Staff Responsibilities

NIOSH will have substantial scientific programmatic involvement during conduct of this activity, through technical assistance, advice, and coordination.

a. Serve as a scientific liaison between the awardee and other program staff at NIOSH with experience in the occupational health issues of MSDs and epidemiology.

b. Provide expert consultation in the area of occupational epidemiology.

c. Provide technical advice on monitoring of field data collection, developing operating guidelines, quality control procedures, and developing policies/protocols for dealing with recurrent situations.

d. Facilitate collaborative efforts to compile and disseminate program results through presentations and publications.

e. Assist in the development of human subjects protocols for the CDC Institutional Review Board (if required) and in the preparation of OMB (and other) clearances that may be required during the conduct of the study.

3. Collaborative Responsibilities

The Coordination Committee will serve as the main governing board for the cooperative agreements making up the MSDC. NIOSH scientists and one external scientist from each award will have membership on the Coordination Committee. One critical role of the CC is to ensure that the study designs and data collection protocols are uniform and compatible across the MSDC.

The Coordination Committee may invite, when it deems it to be necessary, additional, non-voting scientific advisors to the meetings at which research priorities and opportunities are discussed.

It is anticipated that there will be two Coordination Committee meetings each year. Locations of the meetings will be determined by the CC. The committee chair (NIOSH representatives will not serve in this position) will schedule the meetings and will be responsible for developing the meeting agenda, chairing the meetings, and producing CC reports.

At the Coordination Committee meetings, the Coordination Committee will: 1) make recommendations on the study protocols and data collection approaches, 2) discuss the study populations that have been/will be recruited, 3) identify and recommend solutions to unexpected study problems and 4) discuss ways to efficiently coordinate and combine common study activities. These recommendations will be of direct benefit to the awardees by improving the scientific quality and comparability of their research.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into two areas: scientific/research, peer review and financial or grants management issues. This RFA and other CDC Announcements can be found on the CDC HomePage (<http://www.cdc.gov>) under the "Funding" section (see "Grants and Cooperative Agreements" scroll down to "Occupational Safety and Health"). This RFA can also be found on the NIOSH HomePage (<http://www.cdc.gov/niosh>) under "Extramural Programs", "Current Funding Opportunities".

Direct inquiries regarding programmatic issues to:

Lee M. Sanderson, Ph.D.
Scientific Program Administrator
Office of Extramural Programs
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
1600 Clifton Road, N.E.
Executive Park Building 24, Room 1429, MS E-74
Atlanta, GA 30333
Telephone: (404) 498-2546
FAX: (404) 498-2571
Email: lsanderson@cdc.gov

Direct your questions about peer review issues to:

Pervis C. Major, Ph.D.
Scientific Review Administrator
Office of Extramural Programs
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
1095 Willowdale Road
Morgantown, WV 26505
Telephone: 304-285-5979
Fax: 304-285-6147
Email: pmajor@cdc.gov

Direct inquiries regarding grants management business matters to:

Larry Guess
Acting Chief
Acquisition and Assistance Field Branch
Centers for Disease Control and Prevention
626 Cochran's Mill Road
Pittsburgh, Pennsylvania 15236-0070
Announcement Number OH-03-006
Telephone: (412) 386-6826
Email: lguess@cdc.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

- o Descriptive title of the proposed research
- o Name, address, and telephone number of the Principal Investigator
- o Names of other key personnel
- o Participating institutions
- o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of an application, the information that it contains is used to estimate the potential review workload and plan the review.

The letter of intent should be sent to by the date listed at the beginning of the document. The letter of intent should be sent to:

Pervis C. Major, Ph.D.
Scientific Review Administrator
Office of Extramural Programs
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
1095 Willowdale Road
Morgantown, WV 26505
Telephone 304-285-5979
Fax 304-285-6147
Email: pmajor@cdc.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov. Information to prepare a detailed budget is provided in the instructions. If the proposed project involves organizations or persons other than those affiliated with the applicant organization, letters of support and/or cooperation must be included.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS: Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular grant format. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in \$25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the

application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at:

<http://grants.nih.gov/grants/funding/phs398/labels.pdf>

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies, in one package to:

Center for Scientific Review (CSR)
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must also be sent to:

Pervis C. Major, Ph.D.
Scientific Review Administrator
Office of Extramural Programs
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
1095 Willowdale Road
Morgantown, WV 26505
Telephone 304-285-5979
Fax 304-285-6147
Email: pmajor@cdc.gov

APPLICATION PROCESSING: Applications must be received on or before the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

The Center for Scientific Review (CSR) and NIOSH will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to an RFA, it is to be prepared as a NEW application. That is the application for the RFA must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes. While the investigator may still benefit from the previous review, the RFA application is not to state explicitly how.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by CSR and responsiveness by NIOSH. Incomplete applications will be returned to the applicant without further consideration.

Incomplete applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by a scientific review group convened by NIOSH in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

- o Receive a written critique
- o Undergo a process in which only those applicants deemed to have the highest scientific or technical merit, generally the top half of the applications under review, will be discussed and assigned a priority score level of review by the NIOSH Secondary Review Committee.

REVIEW CRITERIA

The criteria that NIOSH will use to review applications for scientific merit and for meeting program objectives are provided below. In the written comments, reviewers will be asked to discuss the following aspects of your application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment

The scientific review group will address and consider each of these criteria in assigning your application's overall score, weighting them as appropriate for each application. Your application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example you may propose to carry out important work that by its nature is not innovative but essential to move a field forward.

SIGNIFICANCE: Does this study address an important problem in the area of work-related musculoskeletal disorders? If the aims of the applications are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field? Will the proposed research contribute to the overall aim of better defining the exposure-response relationships between varying levels of job physical stressors and low back disorders?

APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternatives? Does the recruitment plan address the need to enroll workers with a range of exposure to the physical demands of

lifting and manual material handling (high, medium and low) to have sufficient exposure contrast to assess exposure response? Is the plan for assembling work sites and participants suitable for this study? Will these worksites provide participants who will be representative of the US workforce? Does the project employ standardized, comparable approaches for exposure assessment such as the NIOSH Lifting Equation? Is the time line for the studies appropriate and well described? Are the methods for assuring privacy and maintaining confidentiality of participant records, including specific protections for computerized data systems adequate? Is there adequate consideration of follow up of study participants to assess changes in exposure and health outcomes?

Does the proposed project provide an appropriate approach for maintaining participation over the study time period? Is there adequate consideration of data design and analysis issues related to prospective studies of musculoskeletal disorders, such as sample size, drop outs, multiple comparisons, and recurrent and episodic health outcomes?

INNOVATION: Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies? Are the investigators open to coordinating methods of data collection and analysis with other MSDC consortium members?

INVESTIGATORS: Are the Principal Investigator, Co-Principal Investigators and their teams appropriately trained and have adequate experience to conduct both exposure and health assessments in order to evaluate exposure response? Does the team have a multidisciplinary background to design and conduct a prospective epidemiologic field study? Is the work proposed appropriate to the experience level of the principal investigator and his/her collaborators?

ENVIRONMENT: Does the scientific environment in which the work will be done significantly contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support to facilitate and maintain a high response rate? Does the proposed project utilize an existing resource or constitute a new one?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below).

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria in the sections on Federal Citations, below).

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

ADDITIONAL CONSIDERATIONS

DATA SHARING: The adequacy of the proposed plan to share data.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

PROGRAMMATIC REVIEW CRITERIA

(1) Magnitude and severity of the condition (problem) in the worker population.

(2) Likelihood of developing applied technical knowledge for the prevention of occupational safety and health hazards on a national or regional basis.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: May 20, 2003

Application Receipt Date: June 12, 2003

Earliest Anticipated Award Date: September 30, 2003

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

- o Scientific and technical merit
- o Availability of funds
- o Programmatic priorities

REQUIRED FEDERAL CITATIONS

OFFICE OF MANAGEMENT AND BUDGET CLEARANCE: Projects that involve the collection of information from ten or more individuals and are funded by this cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

All awardees of CDC grants and cooperative agreements and their performances sites engaged in human subjects research must file an assurance of compliance with the regulations and have continuing reviews of the research protocol by appropriate institutional review boards.

In order to obtain a federal-wide Assurance (FWA) of Protection for Human Subjects, the applicant must complete an on-line application at

the Office for Human Research Protections (OHRP) website or write to the OHRP for an application. OHRP will verify that the signatory official and the Human Subjects Protections Administrator have completed the OHRP Assurance Training/Education Module before approving the FWA. Existing Multiple Project Assurances (MPAs), Cooperative Project Assurances (CPAs), and Single Project Assurances (SPAs) remain in full effect until they expire or until December 31, 2003, whichever comes first.

To obtain a FWA contact the OHRP at:
<http://ohrp.osophs.dhhs.gov/irbasur.htm>
or write to:

Office for Human Research Protections (OHRP)
Department of Health and Human Services
6100 Executive Boulevard, Suite 3B01, MSC 7501
Rockville, Maryland 20892-7507
(Note: For Express or Hand Delivered Mail, Use Zip Code 20852)

Note: In addition to other applicable committees, Indian Health Service (IHS) institutional review committees must also review the project if any component of IHS will be involved with or will support the research. If any American Indian community is involved, its tribal government must also approve the applicable portion of that project.

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines are available at: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-

defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at <http://grants.nih.gov/grants/funding/children/children.htm>

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: to "REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS"

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION:

The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

LOBBYING RESTRICTIONS: Applicants should be aware of restrictions on the use of Health and Human Services (DHHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, no part of the Center for Disease Control and Prevention (CDC) appropriated funds shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

Any activity designed to influence action in regard to a particular piece of pending legislation would be considered lobbying. That is lobbying for or against pending legislation, as well as indirect or grass roots: lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, NIOSH/CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies.

The provisions are not intended to prohibit all interaction with the legislative branch, or to prohibit educational efforts pertaining to public health. Clearly there are circumstances when it is advisable and permissible to provide information to the legislative branch in order to foster implementation of prevention strategies to promote public health. However, it would not be permissible to influence, directly or indirectly, a specific piece of pending legislation.

It remains permissible to use NIOSH/CDC funds to engage in activity to enhance prevention; collect and analyze data; publish and disseminate results of research and surveillance data; implement prevention strategies; conduct community outreach services; provide leadership and training; and foster safe and healthful environments.

Recipients of NIOSH/CDC grants and cooperative agreements need to be careful to prevent NIOSH/CDC funds from being used to influence or promote pending legislation. With respect to conferences, public events, publication, and "grass roots" activities that relate to specific legislation, recipients of NIOSH/CDC funds should give attention to isolating and separating the appropriate use of NIOSH/CDC funds from non-NIOSH/CDC funds. NIOSH/CDC also cautions recipients of NIOSH/CDC funds to be careful not to give the appearance that NIOSH/CDC funds are being used to carry out activities in a manner that is prohibited under Federal law.

SMALL, MINORITY, AND WOMEN-OWNED BUSINESS: It is a national policy to place a fair share of purchases with small, minority and women-owned business firms. The Department of Health and Human Services is strongly committed to the objective of this policy and encourages all recipients of its grants and cooperative agreements to take affirmative steps to ensure such fairness. In particular, recipients should:

1. Place small, minority, women-owned business firms on bidders mailing lists.
2. Solicit these firms whenever they are potential sources of supplies, equipment, construction, or services.
3. Where feasible, divide total requirements into smaller needs, and set delivery schedules that will encourage participation by these firms.
4. Use the assistance of the Minority Business Development Agency of the Department of Commerce, the Office of Small and Disadvantaged Business Utilization, DHHS, and similar state and local offices.

RESEARCH INTEGRITY: The signature of the institution official on the face page of the application submitted under this Program Announcement is certifying compliance with the Department of Health and Human Services (DHHS) regulations in Title 42 Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science." The regulation places several requirements on institutions receiving or applying for funds under the PHS Act that are monitored by the DHHS Office of Research Integrity's (ORI) Assurance Program.

For examples:

Section 50.103(a) of the regulation states: "Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary (DHHS) that the applicant: (1) Has established an administrative process, that meets the requirements of this subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and (2) Will comply with its own administrative process and the requirements of this Subpart." Section 50.103(b) of the regulation states that: "an applicant or recipient institution shall make an annual submission to the [ORI] as follows: (1) The institution's assurance shall be submitted to the [ORI], on a form prescribed by the Secretary,...and updated annually thereafter...(2) An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe."

HEALTHY PEOPLE 2010: CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a national activity to reduce morbidity and mortality and improve the quality of life. This RFA is related to one or more focus areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.healthypeople.gov/>

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance under 93.262: Occupational Safety and Health Research Grants at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. This program is authorized under the Public Health Service Act, as amended, Section 301(a) [42 U.S.C. 2419a)], and the Occupational Safety and Health Act of 1970, Section 20(a) {29 U.S.C. 669(a)}. The applicable program regulation is 42 CFR Part 52. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>

SMOKE-FREE WORKPLACE: The PHS/CDC/NIOSH strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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